

REMARKS

Status Summary

Claims 1-4, 6-24, 26-56 and 62-72 are pending in the present application. Claims 62-66 and 68-72 were previously withdrawn. Claims 5, 25, and 57-61 were previously canceled. Claims 1-4, 6-24, 26-56 and 67 stand rejected. With this Amendment, claims 2-4, 6-11, 14, 21-23, 33, 35, 45, 46, 48-52 and 54-56 are canceled. Independent claims 1, 47 and 67 are amended herein. New claims 73-80 have been added. Thus, upon entry of this amendment, claims 1, 12, 13, 15-20, 24, 26-32, 34, 36-44, 47, 53, 62-66, and 67-80 will be pending. Applicants respectfully submit that no new matter has been added. Reconsideration of the application is respectfully requested.

Claim Rejections - 35 U.S.C. § 112

Claims 1-4, 6-24, and 26-56 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention.

Applicants respectfully submit that the rejections under 35 U.S.C. § 112, second paragraph, have been addressed above in the amended claims. Claims 1 and 47 have been amended to overcome the rejection. Claims 2-4, 6-11, 14, 21-23, 33, 35, 45, 46, 48-52 and 54-56 have been canceled. Claims 12, 13, 15-20, 24, 26-32, 34, and 36-44 depend from claim 1 and claim 53 depends from claim 47. The amendments to claims 1 and 47 address the issues under 35 U.S.C. § 112, second paragraph, with regards to claims 12, 13, 15-20, 24, 26-32, 34, 36-44 and 53. Thus, Applicants respectfully submit

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that the rejections under 35 U.S.C. § 112, second paragraph, should be withdrawn and the claims allowed at this time.

Claim Rejections – 35 U.S.C. § 103

Claims 1-4, 6, 7, 9-15, 17, 18, 20-34, 47-56 and 67 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,408,330 to DeLaHueriga (hereinafter, "DeLaHueriga") in view of U.S. Patent No. 6,294,999 to Yarin et al. (hereinafter, "Yarin"). Claims 35-46 are rejected under 35 U.S.C. § 103(a) as being unpatentable over DeLaHueriga in view of official notice previously taken by the Examiner. Claims 8, 16 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over DeLaHueriga in view of U.S. Patent No. 6,083,248 to Thompson (hereinafter, "Thompson"). These rejections are respectfully traversed.

Independent claim 1 recites a system for the delivery of a respirable medicament and the remote assessment of a patient's respiratory condition. The system includes a network computer system having specifiable network addresses. The system includes a patient electronic data collection system that is remote from the network computer system. The patient electronic data collection system is for locally collecting data relevant to the patient's respiratory condition responsive to a sensor of the system which is able to sense the breath of a patient and communicate breath data to the patient electronic data collection system. The system also includes a communicator for wirelessly communicating with an entrypoint to the network computer system to enable transfer of the data to the network computer system, where the data includes a patient identifier. Additionally, the system includes a secure access gateway permitting access

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to the data on the network computer system in response to a user authorization command. The patient electronic data collection system forms part of a medicament delivery system that is arranged to provide respirable delivery of medicament to the patient, that is under the control of the patient, that includes the sensor and that is arranged to collect data when the patient uses the medicament delivery system.

Independent claim 47 recites a method for delivery of respirable medicament and remotely assessing a patient's respiratory condition. The method includes providing a patient with a medicament delivery system that provides respirable delivery of medicament to the patient and that is under the control of the patient. The medicament delivery system includes (i) a sensor to sense the breath of a patient when the patient uses the medicament delivery system, and (ii) a patient electronic data collection system for locally collecting data relevant to the patient's respiratory condition when the patient uses the medicament delivery system in response to the sensor communicating breath data thereto. The method includes using the medicament delivery system by the patient so that (i) the patient receives the medicament, and (ii) the patient electronic data collection system locally collects data relevant to the patient's medical condition in electronic form in response to the sensor communicating breath data thereto. The method also includes wirelessly communicating with an entry point to a remote network computer system to enable transfer of the data to the remote network computer system. Additionally, the method includes permitting authorized user access to the data on the remote network computer system via a secure access gateway.

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Independent claim 67 recites a system for delivery of respirable medicament and the remote assessment of a patient's respiratory condition. The system includes a network computer system having specifiable network addresses. The system includes a patient electronic data collection system that is remote from the network computer system. The patient electronic data collection system is for locally collecting data relevant to the patient's respiratory condition responsive to a sensor of the system which is able to sense the breath of a patient and communicate breath data to the patient electronic data collection system. Additionally, the system includes a communicator for wirelessly communicating with an endpoint to the network computer system to enable transfer of the data to the network computer system, wherein the data includes a patient identifier. The system further includes a secure access gateway permitting access to the data on the network computer system in response to a user authorization command. The patient electronic data collection system forms part of a medicament delivery system that is arranged to provide respirable delivery of medicament to the patient and is arranged to collect data when the patient uses the medicament delivery system. A patient-remote datasource is made available to the network computer system such that information relating to changes to prescription details is transferable thereto.

Applicants respectfully submit that DeLaHuerga and Yarin do not render independent claims 1, 47, and 67, or the claims that depend therefrom, *prima facie* obvious, because the Examiner has failed to make a finding that the prior art included each element claimed in these independent claims as amended. For example,

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DeLaHueriga and Yarin, alone or in combination, do not disclose, teach, or suggest a medicament delivery system that can be used to deliver medicament based on sensing breath.

DeLaHueriga discloses an information system network and method for use thereof for remotely gathering information and storing the information at specific network memory locations for easy access. The system includes at least one remote information collecting device ("ICD") and a network including an input device and a memory storage device. The ICD, in remotely gathering information and based on the information gathered, generates storage addresses and browser configuration information to enable easy review and modification of collected information and subsequent storage. The ICD is to be used with other "smart" devices in a medical facility to collect information which describes facility events. For example, one smart device may be an IV pump which includes a processor, a memory and a transmitter. During a patient's stay in a facility, if the IV pump is connected to the patient, the pump processor monitors all pump activity including type and amount of fluid dispensed and time of administration. Information collected by the pump is assembled into an information segment. When a physician visits the patient, the pump processor transmits the information segment to the physician's ICD. Other smart devices disclosed include a medical container that informs the ICD when it is opened and a patient identification bracelet. Further, DeLaHueriga discloses that the smart device may be a ventilator.

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Yarin discloses systems and methods for facilitating effective self-management of medication treatment by patients. A Smart Tray monitors and reports to third parties a patient's compliance with various medication treatment regimens. Medication containers are provided with electromagnetic tags that provide various information about medicament contained within a respective container. A Smart Tray is equipped with a processor and reader that interrogates each respective electromagnetic tag to identify medicament(s) contained within each container. Using the retrieved information, a Smart Tray provides visual and/or audio signals to a patient to remind the patient when and how much of various medicaments to take. A Smart Tray also monitors, via the reader, when a medication container is removed. A Smart Tray can communicate with one or more third parties, such as healthcare providers, pharmacies, and other suppliers of healthcare products and services via a computer network. In addition, a Smart Tray can communicate with various appliances and can modify medication regimens for particular medicaments in response to data received from various appliances.

While DeLaHueriga discloses a ventilator, it does not disclose a medicament delivery system that can be used to deliver medicament based on sensing breath. A ventilator is a machine to mechanically move air into and out of the lungs of a patient. Thus, the reference to a ventilator in DeLaHueriga does not satisfy the requirement in the amended claims for a **medicament delivery system**. Similarly, Yarin does not disclose teach or suggest a medicament delivery system that can be used to deliver medicament based on sensing breath. Yarin only discloses a smart tray to be used by

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the patient to tell it when to take medication with the smart tray monitoring the removal of medication containers from the tray.

Thus, neither DeLaHueriga nor Yarin, alone or in combination, discloses, teaches or suggests a medicament delivery system that can be used to deliver medicament based on sensing breath. Therefore, neither DeLaHueriga nor Yarin, alone or in combination, render independent claims 1, 47, or 67 *prima facie* obvious. Claims 12, 13, 15, 17, 18, 24, 26-32, and 34 depend claim 1. Claim 53 depends from claim 47. Thus, claims 12, 13, 15, 17, 18, 24, 26-32, 34, and 53 are also not rendered obvious by DeLaHueriga and Yarin, alone or in combination.

Claims 36-44 stand rejected based on DeLaHueriga in view of official notice taken by the Examiner. Regarding the rejection of claims 36-44 of the present application, it is noted that claims 36-44 depend from claim 1. For the reasons set forth above, applicants respectfully submit that DeLaHueriga fails to disclose, teach, or suggest each and every feature recited by claim 1. The official notice taken by the Examiner does not overcome the significant shortcomings of DeLaHueriga described above. In particular, the official notice taken by the Examiner and DeLaHueriga do not disclose, teach, or suggest a medicament delivery system that can be used to deliver medicament based on sensing breath. Thus, claims 36-44 are not rendered obvious by DeLaHueriga in view of official notice taken by the Examiner.

In addition to and independent of the above comments regarding claims 36-44, applicants respectfully disagree with the Examiner's assertion that a lack of response to

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the earlier official notice is an admission by the applicants that the official notice constitutes prior art.

Claims 8, 16, and 19 stand rejected based on DeLaHuerga in view of Thompson. It is noted that claims 8, 16, and 19 depend from claim 1. For the reasons set forth above, applicants respectfully submit that DeLaHuerga fails to disclose, teach, or suggest each and every feature recited by claim 1. Thompson does not overcome the significant shortcomings of DeLaHuerga described above. Thompson discloses a system for communicating with a medical device implanted in an ambulatory patient and for locating the patient in order to selectively monitor device function, alter device operating parameters and modes and provide emergency assistance to and communications with a patient. DeLaHuerga and Thompson, alone or in combination, do not disclose, teach, or suggest a medicament delivery system that can be used to deliver medicament based on sensing breath. Thus, claims 8, 16, and 19 are not rendered obvious by DeLaHuerga in view of Thompson.

Therefore, for at least the reasons stated above, applicants respectfully submit that claims 1, 12, 13, 15-20, 24, 26-32, 34, 36-44, 47, 53, and 67 are not rendered obvious by the cited references or official notice taken by the Examiner. Thus, applicants respectfully submit that the rejections of claims 1, 12, 13, 15-20, 24, 26-32, 34, 36-44, 47, 53, and 67 under 35 U.S.C. § 103(a) should be withdrawn and the claims allowed at this time.

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V. New Claims

New claims 73-80 have been added by this amendment as indicated above. Claims 73-76 depend from claim 1 and claims 77-80 depend from claim 47. Since claims 1 and 47 are not anticipated or rendered obvious by the cited references, claims 73-80 are also not anticipated or rendered obvious by these references. Further, the cited references do not disclose, teach, or suggest the features recited in claims 73-80. Thus, claims 73-80 are allowable over the cited references. No new matter has been added by way of these additional claims.

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CONCLUSION

In light of the above remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

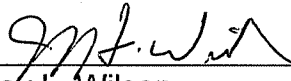
DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. **50-0426**.

Respectfully submitted,

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